

इंटरनेट

मानक

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“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 11318 (1985): Bronchoscope, Aspirating, Negus' Pattern
[MHD 4: Ear, Nose and Throat Surgery Instruments]



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“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

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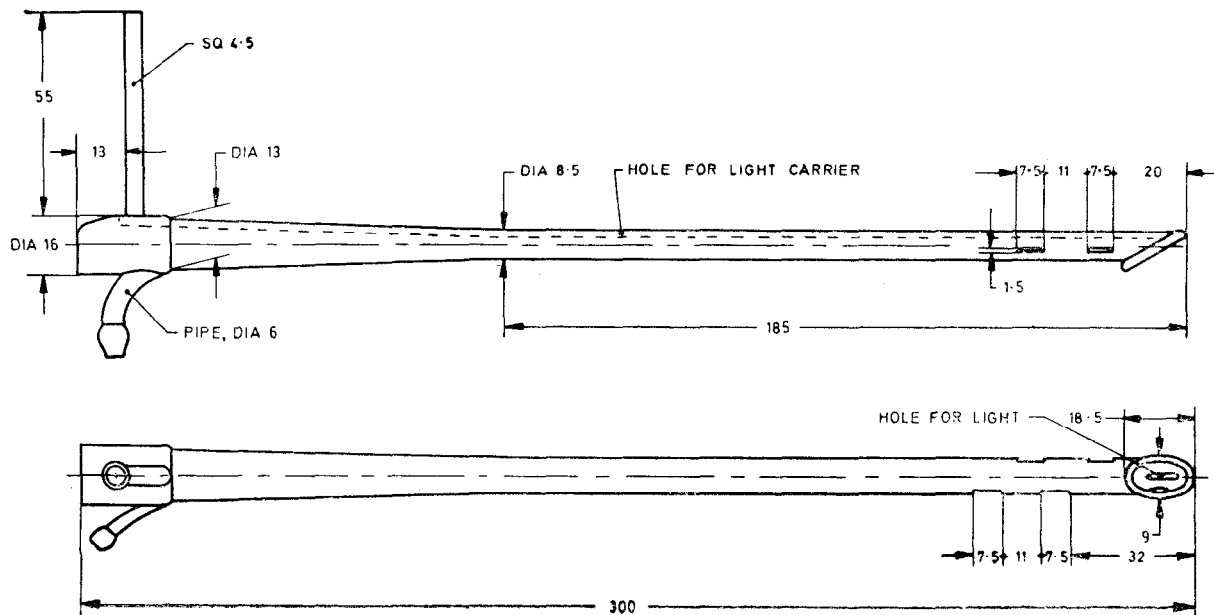
Indian Standard

SPECIFICATION FOR BRONCHOSCOPE, ASPIRATING, NEGUS' PATTERN

1. Scope — Specifies material, dimensions and other requirements for Negus' pattern of aspirating bronchoscope with conventional lighting used for diagnostic purposes in ENT surgery.

2. Shape and Dimensions

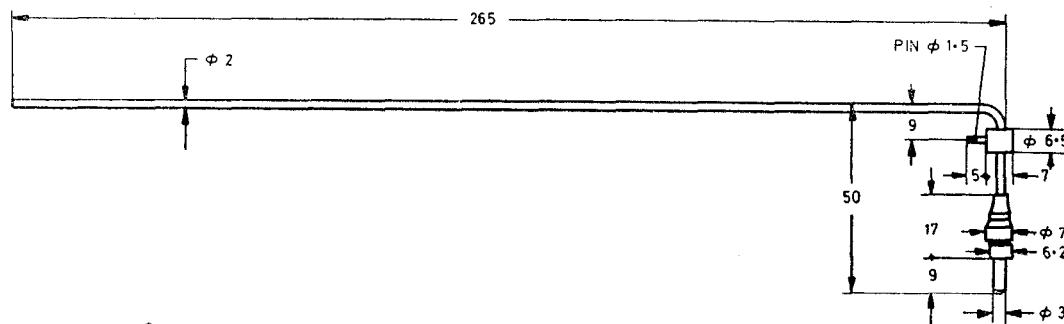
2.1 The general shape and dimensions of bronchoscope and the light carrier shall be as shown in Fig. 1 and 2.



	Lumen	External Diameter	Circumference	Length
Infant	5·4 × 4·1	6	19·5	275
Child	6·5 × 5·2	7·5	26	300
Adult	7·5 × 6·2	8·5	29	400

All dimensions in millimetres.

FIG. 1 BRONCHOSCOPE, NEGUS' PATTERN



All dimensions in millimetres.

FIG. 2 LIGHT CARRIER

Adopted 28 May 1985

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Gr 2

2.1.1 Tolerances on linear dimensions shall be permitted as given below:

- a) ± 0.1 mm on dimensions up to 10.0 mm,
- b) ± 0.5 mm on dimensions above 10.0 mm and up to 25.0 mm,
- c) ± 1.0 mm on dimensions above 25.0 mm and up to 50.0 mm,
- d) ± 1.5 mm on dimensions above 50.0 mm and up to 100.0 mm, and
- e) ± 2.0 mm on dimensions above 100.0 mm.

2.1.2 Tolerance on angular dimension shall be $\pm 1^\circ$.

2.2 *Bulb* — The bulb shall be of rating 2.5 or 3 volts and 0.3 amperes.

2.3 *Locking Mechanism* — The pin (*see* Fig. 1) of the locking mechanism of light carrier shall be such that it is possible to secure it to the handle of the bronchoscope conveniently and quickly.

3. Material — Brass sheet of designation CuZn30 conforming to IS : 410-1977 'Cold rolled brass sheet, strip and foil (*third revision*)' or stainless steel sheet of designation 30Cr13 conforming to IS : 1570 (Part 5)-1972 'Schedules for wrought steels for general engineering purposes: Part 5 Stainless and heat-resisting steel'.

4. Workmanship and Finish

4.1 A protective coating, if stipulated for brass parts shall be plated chromium over nickel conforming to Service Grade No. 2 of IS : 4827-1968 'Electroplated coatings of nickel and chromium on copper and copper alloys (*first revision*)'.

4.2 The surface of bronchoscope shall be smooth and free from burs, pits, cracks and other surface defects.

4.3 All the edges shall be even and rounded.

4.4 The soldering of aspirating tube and brazing of anaesthetic tube to the main tube shall be neat and sound.

4.5 The breathing holes shall be clean and uniform in shape. The edge of the hole shall be smooth.

4.6 The lighting shall be sufficiently intense and shall fall on the tip so that the inner part of bronchus is easily visible.

4.7 The light shall be so placed that it does not obstruct the viewing of the internal organs.

5. Hardness

5.1 The bronchoscope if made of stainless steel shall be uniformly hardened and tempered to a hardness of 400 to 500 *HV*, when tested in accordance with IS : 1501 (Part 1)-1984 'Method for Vickers hardness test for metallic materials Part 1 *HV* 5 to *HV* 100'.

6. Tests

6.1 *Corrosion Resistance* — The bronchoscope if made of stainless steel shall be tested by the method specified in IS : 7531-1975 'Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments. It shall show no sign of corrosion after the test.

7. Sampling and Criteria for Conformity

7.1 *Lot* — In any consignment, all the bronchoscopes produced from the same material, under similar conditions shall constitute a lot.

7.2 The number of bronchoscopes to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

TABLE 1 SAMPLING AND CRITERIA FOR CONFORMITY

(Clause 7.2)

Lot Size (1)	Sample Size (2)
Up to 15	2
16 to 50	3
51 to 150	5
151 and above	8

7.2.1 These bronchoscopes shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS : 4905-1968 'Methods for random sampling, may be followed.

7.3 Number of Tests and Criteria for Conformity — All the bronchoscopes selected at random in accordance with col 1 and 2 of Table 1 shall be tested for shape and dimensions (*see 2*), workmanship and finish (*see 4*). The lot shall be considered as conforming to these requirements if none of the bronchoscopes in the sample is found to be defective in any of these tests.

8. Marking — Each bronchoscope shall be legibly and indelibly marked with the following information:

- a) Size indicating its use for infants, children or adults;
- b) Length;
- c) Manufacturer's name, initials or registered trade-mark; and
- d) Country of manufacture.

8.1 ISI Certification Marking — Details available with the Indian Standards Institution.

9. Packing — As agreed to between the purchaser and the supplier.